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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,858	03/14/2002	Bonnie M. Davis	U 013913-4	4479

140 7590 03/19/2008

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
03/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/099,858	**Applicant(s)** DAVIS, BONNIE M.	
	Examiner Renee Claytor	**Art Unit** 1617	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 February 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3,4 and 38*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see Continuation sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617

Applicant's arguments over the 35 USC 112 first paragraph rejections have been fully considered and are not found persuasive. In particular, Applicants argue that the present invention does not involve treatment of Alzheimer's disease but a totally different condition resulting from low LDL. Applicants assert that the applicant should be permitted to claim the invention in broad terms. Applicants have amended claim 1 to limit to a nicotinic allosteric potentiator; however, as was discussed in the rejection, the specification provides no working examples that all nicotinic allosteric potentiators will effectively treat all cognitive dysfunctions. Further, cognitive dysfunction encompasses many different dysfunctions that may include Alzheimer's or Parkinson's disease amongst other dysfunctions. In addition Applicants have amended claims one to specifiy that the treatment is for those than than one being treated for Alzheimer's disease. However, as discussed in the rejection, there is no teaching in the specification that the treatment is not intended for those who are being treated for Alzheimer's. Accordingly, the rejections are maintained. Applicants have amended the claims to exclude a neuromuscular dysfunction and accordingly the 35 USC 112 second paragraph rejection is hereby withdrawn. Regarding the 35 USC 103 rejections, the Applicants assert that the claims exclude patients who are being treated for Alzheimer's disease. However, the claim language reads on a method for treating a cognitive dysfunction, which includes Alzheimer's disease, of a patient associated with low LDL-cholesterol values in serum by modulation of nicotinic receptors. The rejection addresses this by pointing out that a nicotinic allosteric potentiator such as galanthamine treats a cognitive dysfunction such as Alzheimer's disease and that high serum cholesterol increases the risk of Alzheimer's disease. Accordingly, the rejection reads on the method as written of treating a cognitive dysfunction in a patient associated with low LDL-cholesterol values with a nicotinic allosteric potentiator. Applicants further argue that Kivipelto does not conclude that one should treat Alzheimer's disesase by use of statins and consequently does not teach to treat anyone with combination of an Alzheimer's drug with a statin. In response to this, it is pointed out that Kivipelto was used simply to teach that high serum cholesterol increases the risk of Alzheimer's disease which is evident from the data and concluded on page 1450 under the heading of "The role of cholesterol". Accordingly, the rejections are deemed to read on the present invention.